K020210

APR 3 0 2002

510(k) SAFETY AND EFFECTIVENESS SUMMARY

Prepared:	January 18, 2002
Submitter:	Bayer Diagnostics
Address:	1884 Miles Avenue, P.O. Box 70 Elkhart, IN 46515 (574) 262-6928
Contact:	George M. Tancos, RAC Manager, Regulatory Compliance
Device:	Trade/Proprietary Name: GLUCOMETER® DEX® Diabetes Care System Common/Usual Name: Blood Glucose Meter Blood Glucose Test Sensor Document Control Number: K02 0210
Classification:	Division of Clinical Laboratory Devices Panel – Clinical Chemistry and Toxicology Classification Code – 75CGA (Glucose Oxidase, Glucose)
Predicate Devices:	GLUCOMETER® DEX® Blood Glucose Meter GLUCOMETER® DEX® Test Sensors
Device Description:	The GLUCOMETER® DEX® Diabetes Care System includes: GLUCOMETER® DEX® 2 Blood Glucose Meter GLUCOMTER® DEX® Test Sensors This Diabetes Care System consists of an electrochemical method-based meter and dry reagent sensor (test strips) designed for testing blood glucose by persons with diabetes or by healthcare professionals in the home or in healthcare facilities.

Intended Use:	The GLUCOMETER® DEX® Diabetes Care System is used for the Self-Monitoring of Blood Glucose as an adjunct to the care of persons with diabetes.[1]
Technological Characteristics:	The GLUCOMETER® DEX® Diabetes Care System employs an amperometric glucose oxidase method to measure glucose in blood. It is conceptually the same as other blood glucose monitoring products available for blood glucose testing. The test sensor discs are individually sealed in a package of ten. Blood glucose results are referenced to plasma glucose. The System has a linear response to glucose from 10-600 mg/dL.
Assessment of Performance:	An evaluation of the GLUCOMETER® DEX® Diabetes Care System was conducted in a clinical setting by persons with diabetes. The studies demonstrated that users can obtain blood glucose results from alternate puncture sites that are equivalent to blood glucose results from fingersticks within certain conditions explained in the product labeling.
Conclusion:	The results of clinical evaluations of the GLUCOMETER® DEX® Diabetes Care System demonstrate that the device can produce blood glucose results from alternate puncture sites that are equivalent to blood glucose results from fingersticks within certain conditions explained in product labeling.

[1] "Consensus Statement on Self-Monitoring of Blood Glucose," Diabetes Care, Vol. 10, No. 1, January-February 1987, pp. 95.99

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 3 0 2002

Mr. George M. Tancos
Manager, Regulatory Compliance
Bayer Corporation
1884 Miles Avenue
P.O. Box 70
Elkhart, IN 46515-0070

Re: k020210
Trade/Device Name: GLUCOMETER®DEX Diabetes Care System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: March 28, 2002
Received: March 29, 2002

Dear Mr. Tancos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020210

Device Name: GLUCOMETER® DEX® Diabetes Care System

Indications for Use: The GLUCOMETER® DEX® 2 Blood Glucose Meter and the GLUCOMETER® DEX® Test Sensors are used to measure the glucose levels in whole blood from specimens taken from the fingers or an alternate puncture sites within certain conditions. The GLUCOMETER® DEX® Diabetes Care System is an over-the-counter (OTC) device used by persons with diabetes in a home setting and by healthcare professionals in healthcare facilities. The frequent monitoring of blood glucose is an adjunct to the care of persons with diabetes.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laborato:
510(k) Number K020210

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ **OR** **Over-The-Counter Use** ✓
(Per 21 CFR 801.109)